

Remarks

Claim 63 has been cancelled, and claims 56-62 and 66 have been amended. Claims 41-42, 56-62, 66 and 75-81 are pending.

I. REJECTIONS UNDER 35 U.S.C. §112, ¶1

The examiner rejects claims 41-42 under 35 U.S.C. §112, ¶1, allegedly because the claims are not enabled by the specification.

Under §112, an application must explain how to “make and use” the claimed invention. The courts have interpreted this statute to mean that the specification must teach the skilled artisan how to practice the invention without undue experimentation. *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). Thus, the test is not whether experimentation is necessary, but whether any experimentation would be undue in view of what type and amount of experimentation is typical in the area. *See In re Wands*, 858 F.2d at 736-37 (“Enablement is not precluded by the necessity for some experimentation such as routine screening.”). *See also* MPEP §2164.01 (Feb. 2003) at page 2100-179.

In levying an enablement rejection, the examiner has the burden of establishing why the scope of the claims is not adequately enabled by the specification. *See* MPEP §2164.04 (Feb. 2003), pg. 2100-183. Appellants respectfully argue that the examiner has failed to meet this burden. The examiner has proffered no evidence that one skilled in the art at the time of the invention would need to exert undue experimentation to make and use the invention. Indeed, measuring the activity of associating compounds is among the more basic skills in the art. Moreover, the specification provides instructions and examples for quickly conducting such evaluations. *See* Application pg. 22, ln. 19-26 and pg. 79, ln.7-17. Thus, a rejection of the claims for lack of enablement is improper.

Nevertheless, in an effort to expedite prosecution, applicants have amended the claims and assert that the amendments obviate the rejection.

II. REJECTIONS UNDER 35 U.S.C. §101

The examiner rejects claims 56-63 and 75-81 under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter.

To meet the utility requirement of §101 (and 112) of the Patent Act, an applicant need only show that the claimed invention is "practically useful," (*Anderson v. Natta*, 480 F.2d 1392, 1397 CCPA 1973)) and confers a "specific benefit" on the public. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966). As discussed in a recent Federal Circuit case:

The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. See *Brenner v. Manson*, 383 U.S. 519, 534 [148 USPQ 689] (1966); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 [24 USPQ2d 1401] (Fed. Cir. 1992) ("To violate Section 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention "is incapable of serving any beneficial end").

Juicy Whip Inc. v. Orange Bang Inc., 51 USPQ2d 1700, 1702 (Fed. Cir. 1999).

The present invention easily satisfies this standard. The inventive methods have revolutionized the design of TACE mediators, transforming a costly, time-consuming process into a quick, efficient procedure. Thus, the invention has substantial, real-world utility.

Once a patent applicant identifies a specific utility, the claimed invention is presumed to possess it. *In re Cortright*, 165 F.3d 1353, 1357 (Fed. Cir. 1999); *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995). The Patent Office then bears the burden of demonstrating that a person of ordinary skill in the art would reasonably doubt that the asserted utility could be achieved by the claimed invention. *Id.* If and only if the Patent Office makes such a showing, the burden shifts to the applicant to provide rebuttal evidence that would convince the person of ordinary skill that there is sufficient proof of utility. *Brana*, 51 F.3d at 1566.

Applicants assert that the examiner has failed to satisfy this burden. The examiner argues that "a method which identifies a compound which interacts/associates with TACE does not provide a useful, concrete and tangible result, as the activity of the associating compound, and/or its effect on TACE, is completely unknown." Office Action, pg. 5, 2nd ¶.

So stating, the examiner disavows the substantial benefit afforded by the identification of associating compounds. As noted previously, a process for identifying associating compounds was a major advance in the field, effectively making an onerous task routine. As the inventive methods dramatically reduced the costs and development time of TACE mediators, applicants assert that a person of ordinary skill in the art would not reasonably doubt the utility of the invention.

In an effort to expedite prosecution of the instant case, however, applicants have amended the claims and assert that the amendments obviate the rejection.

In view of the foregoing remarks it is believed that the application is in condition for allowance. A favorable disposition of the application therefore is solicited.

Respectfully submitted,

Brian V. Carl
By Reg No 48,571

Date 22 September 2002

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
CUSTOMER NUMBER

22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5404

Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768